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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,716	08/30/2004	Brian C. Case	PA-5380-RFB	4764
9896	7590	11/09/2007		
COOK GROUP PATENT OFFICE			EXAMINER	
P.O. BOX 2269			STEWART, ALVIN J	
BLOOMINGTON, IN 47402				
			ART UNIT	PAPER NUMBER
			3774	
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			11/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/828,716	Applicant(s) CASE ET AL.	
	Examiner Alvin J. Stewart	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13,17 and 21-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13,17 and 21-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

***Response to Arguments***

Applicant's arguments filed 8/24/07 have been fully considered but they are not persuasive.

Regarding claim 13, the Applicant's representative discloses that the pockets between the leaflets and the wall of the bodily passage is not disclose in the Moll reference. The Applicant's representative discloses that the Moll reference includes pockets that are formed between sheets of the valve material (see Fig. 6 and the description of element 22 at the top of column 4).

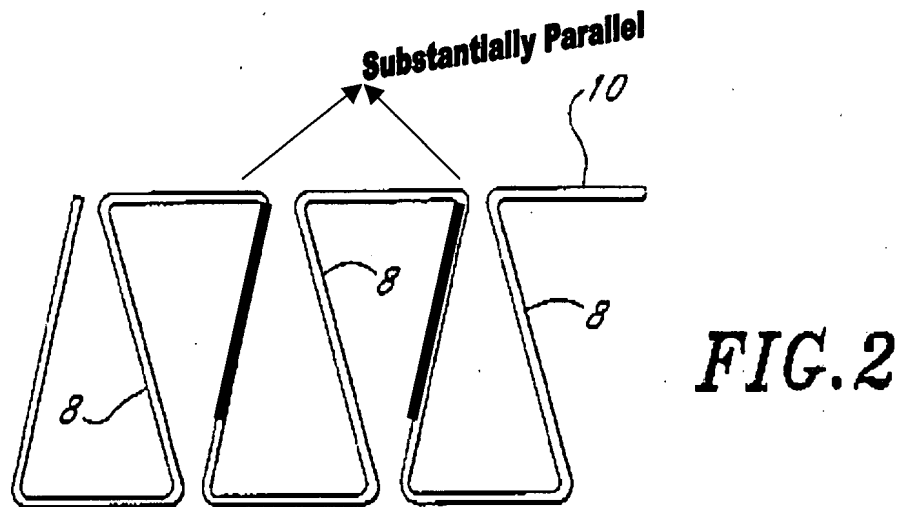
Regarding the above applicant's remarks the Examiner agrees with the Applicant's representative arguments disclosing that the Moll device includes pockets that are formed between sheets of the valve material. However, the Applicant's representative is claiming pockets that are located between the leaflets and the walls of the bodily passage. Therefore, the Moll reference clearly disclose pockets between sheets and clearly disclose pockets between the leaflets and the walls of the bodily passage. For example, see Fig. 1 disclosing pockets (16) between the inner wall (12) of at least one leaflet and the wall of the bodily passage (20) (see Fig. 6). Figure 6 clearly disclose pockets between the leaflets and the walls of the bodily passage.

Finally, the Examiner wants to clarify the interpretation of the Moll device. The implant comprises three stoppage elements (6) around the circumference of the implant, the three elements (6) form a valve structure, each stoppage element comprises an outer wall (14) and a leaflet having an inner wall (12). The outer walls (14) are adapted to be touching the patient's walls of the bodily passage and between the two walls (14 and 12) pockets are created (as disclosed by the Applicant's representative). Therefore, the pockets created from the inner and

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outer walls are also between the leaflets and the patient's vessel walls. For the above reasons the Examiner believes that the rejection is proper.

Regarding claim 17, Figure 2 of the Moll et al reference clearly disclose a first and second substantially parallel longitudinal attachment struts and a pair of opposing leaflets attached there along, see below.



Regarding claims 22 and 23, the meaning of the word "commissure" is a simple junction, therefore, Figure 1 clearly disclose a junction in the distal end of the implant between the structure element 8 and element 14 and element 12.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13, 17, 21-25, 28 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Moll et al US Patent 6,287,334 B1.

Moll et al discloses an artificial heart valve comprising a valve structure having a plurality of leaflets (6), the leaflets having proximal and distal portions, an inner edge traversing the passage, a first and second lateral edges. The edges includes an attachment pathway, the pathway extends along the first and the second edges, each of the first and second lateral edges include a proximal attachment pathway portion.

Additionally, Moll et al discloses a support structure (10) comprising a series of proximal bends comprising commissural points and longitudinal attachment struts extending distally therefrom, the support structure further comprising a pair of distal attachment struts extending distally and circumferentially from the longitudinal attachment struts. The lateral outer edges are attached proximally along the longitudinal attachment struts to form a extensive leaflet contact area and distally long the distal attachment struts which converge laterally and carry the bottom edge of each of the plurality of leaflets such that the prosthesis is adapted for forming a seal between the plurality of leaflets and the walls of the bodily passage and creating a large pocket at the base of each of the plurality of leaflets.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mull et al US Patent 6,287,334 B1 in view of Park et al US Patent 6,669,724.

Mull et al discloses the invention substantially as claimed. However, Mull et al does not disclose a leaflet contact area that comprises 35-55 % of the length of the valve structure.

Park et al teaches a valve prosthesis comprising a plurality of leaflets having an internal wall wherein the amount of contactable or coactable area between the leaflets is between 33 to 55 % of the length of the whole valve system (see Figs. 2 & 4) for the purpose of efficiently avoiding retrograding flow (see col. 1, lines 38-45).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Mull et al reference with the larger coaptive area of the Park et al reference in order to efficiently avoiding retrograding flow.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*A. Stewart*  
**ALVIN J. STEWART**  
**PRIMARY EXAMINER**  
Art Unit 3774

November 07, 2007.